REMARKS

Claims 1-16, 19-22, and 25-27 had previously been pending in the current application. Claim 27 has been canceled. Reconsideration and allowance of these previously pending claims and the newly added claims is respectfully requested in view of the amendment to claim 27 and the following remarks.

In support of the rejection of claims 1 through 15, 19, 20, 22, 25 and 26, under 35 USC 112, paragraph one, as purportedly reciting subject matter which is not described in the specification in a manner to enable one skilled in the art to make or use the invention defined by these claims, the examiner contends that the application is enabling for isolating mRNA from soy cotyledons or sprouts, is enabling for transforming corn kernels of corn varieties 27-1 and 85089 using the microinjection technique disclosed in the specification and is enabling for claims drawn to transgenic corn plants and kernels of corn strain 27-1 and 85089 expressing soy globulin. The examiner asserts that the application is not further enabling for producing any transgenic plant which expresses any exogenous protein.

Applicant respectfully disagrees and requests reconsideration. It is simply not the law that an applicant is required to provide an exemplary species for every aspect of the invention which might be embraced by a generic claim. Applicant respectfully submits that applicant's examples manifestly demonstrate practice of the invention, applicant should not be limited in the claim coverage awarded to applicant by the specific examples applicant has included. Applicant is entitled to broad, generic claims for the process which applicant has discovered. Reconsideration and withdrawal of the rejection of claims 1 through 15, 19, 20, 22, 25 and 26, under 35 USC 112, first paragraph, on the basis that the application allegedly fails to disclose the subject matter enabling one of skill in the art to practice the inventions defined by claims 1 through 15, 19, 20, 22, 25 and 26, is respectfully requested.

Respecting the transformation with soy globulin mRNA, the examiner concedes, and applicant appreciates such concession, that the application is enabling for isolating mRNA from soy cotyledons or sprouts. Applicant strongly disagrees with the examiner's

contention that the application is not enabling for isolating and purifying soy globulin mRNA. The examiner believes that one of ordinary skill in the art needs guidance or examples as to how to identify soy globulin mRNA from all of the RNA species. Applicant respectfully notes that applicant isolated total mRNA, which is then microinjected into the seed. Applicant emphasizes that no specific messenger RNA was isolated and in that regard the examiner's attention is directed to page 9, lines 10 through 14 of the specification.

Applicant also most respectfully directs the examiner's attention to page 9, lines 10 and 11 of the specification, where applicant notes that eighty percent (80) of the poly AmRNA in soy encodes soy globulin protein, specifically the 7S and 11s fractions. Hence, since almost all of the mRNA soy encodes the soy globulin protein, it is not necessary to isolate or purify the soy mRNA.

Applicant further notes that the application discloses microinjection of total polyA mRNA from soy sprouts or cotyledons. Applicant asserts that isolation of these is well known to those of skill in the art and thus need not be detailed in the application specification. The law is well settled that the specification need not disclose what is well-known to those skilled in the art and preferably omits that is well-known to those of skilled in the art. *In re Buchner,* 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). Accordingly, applicant again submits that the enablement requirement is met by this application. Applicant respectfully request reconsideration and withdrawal of the 35 USC 112, first paragraph, rejection as regarding claims 1 through 15, 19, 20, 22, 25 and 26.

The Examiner contends that the application is not enabling for a method for producing any transgenic plant which expresses any exogenous protein. . . . Applicant is only enabled for a method of expressing soy globulin protein in corn strains 27-1 and 85089 given the method as described in the specification."

The presence of only one working example should never be the sole reason for rejecting claims as being broader than the enabling disclosure . . .MPEP §2164.02. Further, the scope of enablement need only bear a "reasonable correlation" to the scope of the claims. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). ". . . [S]ince one embodiment . . . and the method . . . is set forth in the specification, the

specification is enabling". *In United States v. Telectronics, Inc.*, 857 F.2d 778, 8 USPQ2d 1217 (Fed. Cir. 1988), *cert. denied,* 499 U.S. 1046 (1989).

An enablement rejection based on the grounds that a disclosed limitation is missing from a claim should be made only when the language of the specification makes it clear that the limitation is critical for the invention to function as intended. MPEP 2164.08(c). Applicant makes no such assertion as to the *essential* or critical nature of any specific corn strain or even of corn for practice of the invention.

The Examiner's attention is respectfully directed to page 18, lines 9-14 of the application where Applicant specifically states that the invention *is not limited to the embodiments disclosed, modifications can be made, and such modifications are well within the skill of those in the art of plant molecular biology* having the benefit of the teaching of the instant application. Thus, the application as filed is enabling for the methods providing a novel and obvious transformation protocol by which to produce transgenic plants.

"To provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose limit his claims to what he has found will work . . . in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts." *In re Goffe,* 542 F.2d 564, 5676, 191 USPQ 429, 431 (CCPA 1976). Applicant has detailed the microinjection of mRNA into a seed, using *two* different strains of corn, for the purpose of creating a seed which will grow into a transgenic plant. The Applicant has further demonstrated, as depicted in figures 1-6, that the method disclosed is operable. An applicant need not describe all embodiments. Embraced by a generic claim MPEP §2164.02.

The invention disclosed provides a method for those skilled in the art to inject an mRNA sample of interest into a seed, which seed has been made amenable to microinjection by presoaking in water (page 9, lines 14-21). Obtaining the mRNA of interest can be by *in vitro* transcription from a DNA template or by isolation and purification of the mRNA. These skills are well known and widely accepted protocols. (see Sambrook et al. (Molecular Cloning--A Laboratory Manual, 2d Edition, Vol. 1-3, Cold Spring Harbor Laboratory, Cold Spring Harbor Press, New York, 1989); and

Current Protocols in Molecular Biology (Ausubel et al., Eds., Current Protocols, 1994 Supplement).).

The transformed seed is then planted in order to germinate. This skill is known to those knowledgeable in the art and thus is described in sufficient detail as to enable those skilled in the art to practice the invention.

To determine whether the plant that has grown from the transformed seed is a transformed plant, those of skill are knowledgeable as to how to isolate total protein from a plant or plant part (for example, the leaves) and probe for the protein of interest using well-known methods such as Western blotting. Some experimentation might be necessary with other plants, but "[A]n extended period of experimentation may not be undue (and hence may not be disabling for patentability) if the skilled artisian is given sufficient direction or guidance" by the disclosure, *In re Colianni*, 561, F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977). [A] considerable amount of experimentation is permissible, if it is merely routine . . . " *In re Angstadt*, 537 F.2d 489, 502-4, 190 USPQ 214, 217-19 (CCPA, 1976).

Applicant has adequately described a novel method that is reproducible by those skilled in the art. "[T]he mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it." 822 F.2d at 1078, 3 USPQ2d at 1302; *In re Chilowsky*, 229 F.2d 457, 461, 108 USPQ 321, 325 (CCPA 1956). In view of the aforementioned authorities Applicant respectfully requests withdraw of the rejection and reconsideration of the claims.

In support of the 35 USC 112, first paragraph rejection of claims 11 through 16, 19 through 22, 25 and 26 the examiner asserts that "the corn strains 27-1 and 85089 claims are essential to the claimed invention . . . This is a mischaracterization of the application. Nowhere in the specification is there a representation or admission that specific corn strains 27-1 and 85089 are essential. The Examiner's attention is respectfully directed to page 13, lines 3-4 wherein Applicant states that two strains of high yield corn, specifically the 27-1 and 85089 strains, have been used. There are many, many strains of corn; Applicant chose these specific strains since they produce a relatively high yield of seeds, thereby providing for a greater number of seeds to treat and

transform as well as a greater number of plants to examine in future generations, all for analyzing the efficacy of transformation.

Additionally, the efficacy of the transformation protocol is detailed in the specification (page 14, lines 14-24; page 15, Table 1; page 16, Table 2; figures 1-6). Thus, applicant has shown the efficacy of the method of the invention using as examples corn strains 27-1 and 85089 together with soy globulin mRNA. Those skilled in the art will now be able to make transgenic plants of many species using the methods disclosed by the Applicant.

The Examiner states "The specification does not disclose a repeatable process to obtain the exact same corn strains 27-1 and 85089. . .". The Applicant respectfully corrects the Examiner in that the corn strains 27-1 and 85089 are not the result of the transformation process but are the corn strains being transformed (page 6, lines 11-13). Applicant chose these corn strains since they are high yield corn strains (page 13, lines 3-4; *supra*). Other corn strains may be used, as well as other plants. One principal aspect of the invention is to *transform a plant in order to produce an exogenous protein*. Corn strains 27-1 and 85089, as well as the soy globulin mRNA, are examples by which the efficacy of the protocol is established. Using the teachings of the application, those skilled in the art would be able to make a transgenic corn plant expressing a soy globulin mRNA; whether or not it was an exact duplicate is irrelevant. The objective is to produce a transgenic plant expressing an exogenous protein of choice. Applicant has adequately fulfilled the enablement requirement of U.S.C. §112 (1) and earnestly requests reconsideration and allowance of the claims.

In support of the 35 USC 112, second paragraph rejection of claims 8, 13, 14, 15, 22 and 25 the examiner has asserted that "the metes and bounds of 'sprouts' has not been defined. Applicant has not specified the age of the sprouts or size. One skilled in the art would not know at what stage of plant development to isolate mRNA given that the RNA profile of an organism changes as the organism develops". Applicant respectfully disagrees. The Examiner is directed to page 9, lines 10-13 where Applicant states that sprouts are the shoot and root axis of the plant (page 9, lines 10-11), and that 80% of the poly A mRNA in soy encodes soy globulin protein.

A sprout is defined as the stage of germination of a seed when a shoot pushes up through the soil and the plant begins to grow. Sprouting is nothing more than taking seeds and supplying them with enough moisture often enough to make them pop open and start to grow. Sprouting, or germination, generally only occurs after a kernel has matured and dried to a harvest ripe stage. Germination then begins when a kernel absorbs water, activating a number of enzymes which break down starch and proteins, producing some basic constituents required for respiration. Sprouting usually takes approximately 2-6 days. This knowledge is commonplace.

It is improper to reject a claim wherein the scope of the claim is clear to a hypothetical person possessing the ordinary level of skill in the pertinent art. MPEP §2171. Applicant contends that the claims are precise and clear and unambiguous to those knowledgeable in the field of plant biology. Applicant respectfully requests reconsideration and allowance of the claims.

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BY: RHONDA BRYANT

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